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September 7, 2004

Dr. Lester Crawford
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Commissioner Crawford:

As you know, I have been following closely the Food and Drug Administration's unsolicited intervention into private state lawsuits on behalf of drug companies and medical device manufacturers being sued by individuals harmed by their products. I believe these activities undermine FDA's primary mission of protecting the public health and must stop. During the course of my research into this issue, however, I have come across a separate matter that reaffirms my belief that FDA is not fulfilling its mandate.

The American public relies on FDA to ensure that they and their physicians have all the necessary information about the potential side effects of a prescription drug. That is why I was troubled to learn that FDA has failed to take any action in response to a growing body of evidence gathered by FDA and outside sources linking the prescription drug Neurontin with attempted and completed suicides. Neurontin is manufactured by Pfizer unit Warner-Lambert, which pleaded guilty this past May to illegally marketing Nuerontin for off-label uses.

Earlier this year, Finkelstein & Partners, a law firm located in my district, contacted FDA about a study it conducted regarding a possible link between Neurontin and suicide among the drug's users with no prior history of mental illness or attempted suicide. When informed of the study results, the Neurontin FDA safety officer felt an "imminent health hazard" might exist. FDA requested a follow-up conference call with the law firm and several FDA officials. During that call, FDA informed the firm that it has the "world's most important data set" regarding the issue of psychiatric adverse events and Neurontin.

Yet despite the evident alarm of several FDA officials, the agency refused to look further into the matter and instead informed the law firm that it should conduct a further comprehensive analysis. This was an extremely unreasonable request and an amazing failure on the part of FDA. Presented with evidence of what an FDA official termed a potential "imminent health hazard," your agency did nothing beyond the one conference call. FDA is obligated to ensure that drugs are safe and effective. When presented with

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evidence of potential harmful side effects, FDA has a duty to examine it and, if necessary, take action to ensure that preventable injuries or fatalities are avoided.

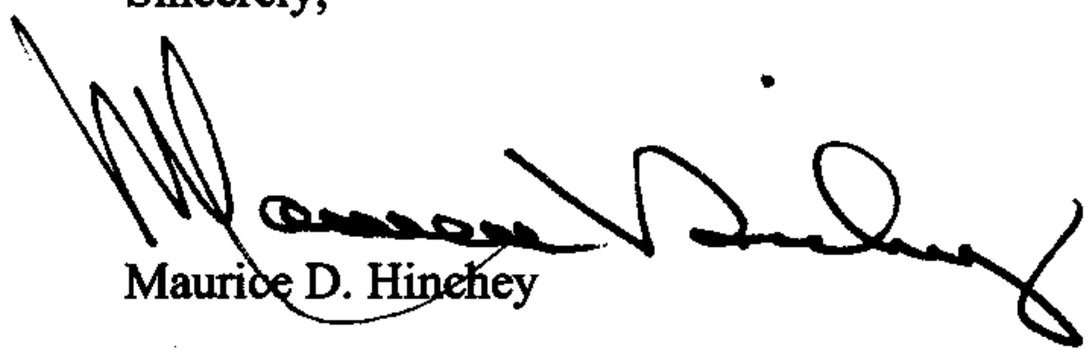
FDA's own post-marketing Adverse Event Reporting System (AERS) has also been collecting information that supports an examination. According to AERS, Neurontin users completed eight suicides between 1998 and 2002 and completed seventeen suicides in the first half of 2003. Again, however, FDA has failed to act.

As a result of FDA's inaction, on May 17 of this year Finkelstein & Partners filed a citizen petition with FDA asking the agency to require that Neurontin's label reflect the number of suicides FDA's AERS has collected. Again, FDA has not acted, other than acknowledging receipt of the petition. According to Title 21 of the Food, Drug and Cosmetic Act, FDA has 180 days to grant, deny, or provide a tentative response to the petition. While FDA has been aware of this issue since March and the Finkelstein citizen petition is one of only four filed this year by a non-drug or medical device manufacturer, the agency has taken no action on this serious matter. Given these realities, FDA should have already begun to take action.

FDA's failure to fully examine evidence of potential harmful side effects of one of its regulated drugs is alarming, especially in light of the fact that its own data supports this conclusion. I hope you will consider the gravity of this matter and immediately initiate a comprehensive examination of the link between Neurontin and suicide. There is too much at stake to allow further delay.

Thank you for your attention to this matter. I look forward to hearing back from you soon.

Sincerely,



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